

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

DMB
Display Date 4-9-02
Publication Date 4-10-02
Certifier R. LEDESMA

Oral Dosage Form New Animal Drugs; Lincomycin Hydrochloride Soluble Powder

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Pharmacia and Upjohn Co. The supplemental NADA provides for the use of lincomycin hydrochloride soluble powder in the drinking water of swine weighing greater than 250 pounds for the treatment of swine dysentery.

DATES: This rule is effective [*insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Janis R. Messenheimer, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7578, e-mail: jmessenh@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Pharmacia and Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001-0199, filed a supplement to NADA 111-636 that provides for use of LINCOMIX (lincomycin hydrochloride) Soluble Powder for making medicated drinking water for the management of various bacterial diseases of swine and chickens. The supplemental NADA provides for replacement of the limitation "Not for use in swine weighing more than 250 pounds" with "The safety of lincomycin has not been demonstrated for pregnant swine or swine intended for breeding." The supplemental application is approved as of December 31, 2001, and the regulations are amended in 21 CFR 520.1263c to reflect the approval. Section 520.1263c is also being revised to reflect current editorial format.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this supplemental application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. Section 520.1263c is amended by revising paragraphs (a), (b), and (d) to read as follows:

§ 520.1263c Lincomycin hydrochloride soluble powder.

(a) *Specifications.* Each gram of soluble powder contains lincomycin hydrochloride equivalent to 0.4 grams of lincomycin.

(b) *Sponsors*. See Nos. 000009, 046573, and 051259 in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

* * * * *

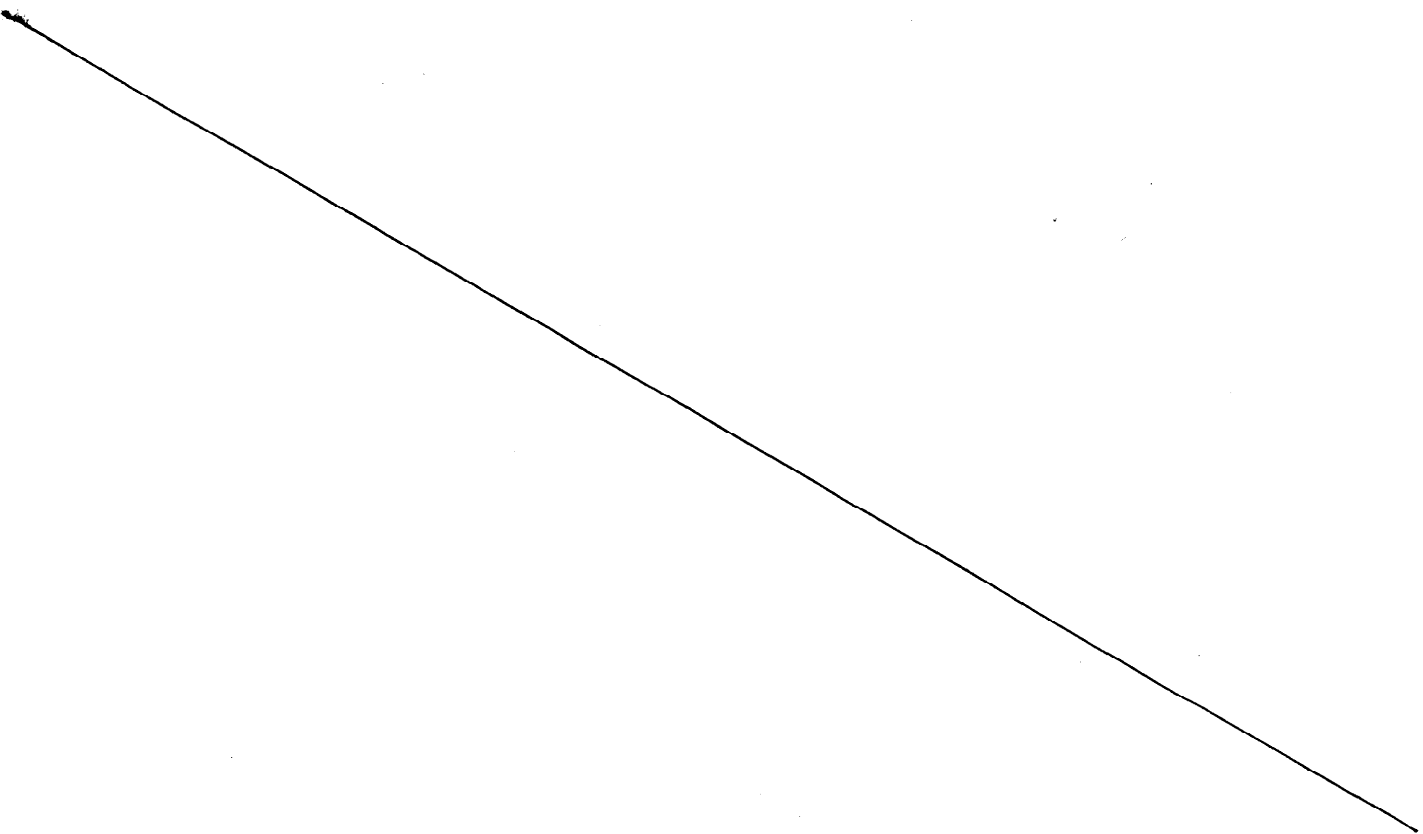
(d) *Conditions of use*—(1) *Swine*—(i) *Amount*. 250 milligrams per gallon of drinking water to provide 3.8 milligrams per pound of body weight per day.

(ii) *Indications for use*. For the treatment of swine dysentery (bloody scours).

(iii) *Limitations*. Discard medicated drinking water if not used within 2 days. Prepare fresh stock solution daily. Do not use for more than 10 days. If clinical signs of disease have not improved within 6 days, discontinue treatment and reevaluate diagnosis. The safety of lincomycin has not been demonstrated in pregnant swine or swine intended for breeding.

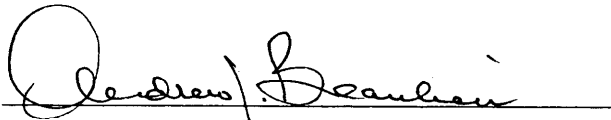
(2) *Chickens*—(i) *Amount*. 64 milligrams per gallon of drinking water.

(ii) *Indications for use*. For the control of necrotic enteritis caused by *Clostridium perfringens* susceptible to lincomycin in broiler chickens.



(iii) *Limitations*. Discard medicated drinking water if not used within 2 days. Prepare fresh stock solution daily. Administer for 7 consecutive days. Do not allow rabbits, hamsters, guinea pigs, horses, or ruminants access to water containing lincomycin. Not for use in layer and breeder chickens.

Dated: March 25, 2002
March 25, 2002.



Andrew J. Beaulieu,
Acting Director, Office of New Animal Drug Evaluation,
Center for Veterinary Medicine.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

BILLING CODE 4160-01-S

**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL**

